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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,445	11/13/2001	A. Neil Barclay	DX 01052K1	1467

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DNAX RESEARCH, INC.
LEGAL DEPARTMENT
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EXAMINER

QIAN, CELINE X

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 02/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,445

Applicant(s)

BARCLAY ET AL.

Examiner

Celine X Qian Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>CRF problem report</u> . |

DETAILED ACTION

Claims 9-23 are pending in the application.

This Office Action is in response to the Amendment filed on 10/4/04.

Response to Amendment

The objection to claim 2 is moot in light of Applicant's cancellation of the claim.

The rejection of claim 2 under 35 U.S.C.101 is moot in light of Applicant's cancellation of the claim.

The rejection of claim 2 under 35 U.S.C.112 1st paragraph is moot in light of Applicant's cancellation of the claim.

The rejection of claim 2 under 35 U.S.C.112 2nd paragraph is moot in light of Applicant's cancellation of the claim.

The rejection of claim 2 under 35 U.S.C.102 (b) is moot in light of Applicant's cancellation of the claim.

The objection to the specification is maintained because the disclosure is not in sequence compliance.

Newly added claims 9-23 are rejected under 35 U.S.C.101 for reasons set forth of the record (as applied to claim 2) mailed on 6/3/04 and further discussed below.

Newly added claims 9-23 are rejected under 35 U.S.C.112 1st paragraph for reasons set forth of the record (as applied to claim 2) mailed on 6/3/04 and further discussed below.

Claims 9-23 are rejected under 35 U.S.C.112 2nd paragraph for reasons discussed below.

Claim 22 is objected to for reasons discussed below.

Sequence Compliance

The communication filed on 10/4/04 is not fully responsive to the office action mailed on 6/3/04 for reasons set forth on the CRF Diskette problem report (see attached). Failure to comply with the requirements set forth in 37 CFR 1.821-1.825 may result in abandonment of the application.

New Grounds of Rejection Necessitated by Applicant's Amendment

Claim Rejections - 35 USC § 101

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 9-23 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, substantial and specific asserted utility or a well established utility.

Claims 9-23 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible, substantial and specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

In response to this rejection, Applicants argue that the specification discloses a specific and substantial utility for the claimed binding compound of claims 9-23. Applicants argue that the specification identifies a number of embodiments where modulation of CD200R would be desirable such as "autoimmunity; an inflammatory condition; tissue specific autoimmunity..." as disclosed on page 74, lines 30-35. Applicants assert that it is readily apparent to one of skill in the art the usefulness of the agents that can modulate activation of macrophages in such disease

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states to ameliorate or mitigate symptoms of such diseases, thus the asserted utility is credible. Applicants further cited Hoek et al. to demonstrate that CD200^{-/-} mice have increased numbers of activated macrophages and a profound increase in susceptibility to autoimmune disease affecting brain and joint. Applicants also cite Gorczynski et al. to show the ability of CD200Fc to ameliorate collagen-induced arthritis in mice, and anti-CD200R antibody elicits immunosuppression which permitting increased allograft survival in mice. Furthermore, Applicants cite Foster-Cuevas et al. to show that signaling through human CD200R down-regulates macrophage activation in the manner predicted by the multitude of murine and rat studies involving CD200/CD200R interactions. Applicants thus conclude that the claimed invention has credible, substantial and specific utility.

These arguments have been fully considered but deemed unpersuasive. The disclosure on page 74, lines 30-35 of the specification is a laundry list for supposedly functions of the CD200R, which does not provide any credible, substantial and specific utility for the claimed invention. Further, the specification teaches that the polypeptide encoded by SEQ ID NO:20 is identified by sequence homology with SEQ ID NO:2, wherein SEQ ID NO:2 is a rat polypeptide that binds to OX2 antigen. As discussed in the previous office action, sequence homology alone cannot accurately predict function of the protein. As such, it is unclear whether SEQ ID NO:20 would have the same function as the protein encoded by SEQ ID NO:2, or those disclosed in the cited references. With regard to Hoek et al., this reference teaches the association between CD200 antigen and autoimmune disease, rather than the specific receptor of CD200R, let alone the a polypeptide comprising a polypeptide encoded by SEQ ID NO:20 (or fragment thereof). With regard to Gorczynski et al., the disclosure of the ability of CD200Fc to ameliorate collagen-

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induced arthritis in mice and anti-CD200R elicits immunosuppression does not provide any information with regard to the utility of the polypeptide encoded by SEQ ID NO:20. Similarly, Foster-Cuevas et al. teach human herpes virus 8 K14 protein mimics CD200 in down-regulating macrophage activation through CD200 receptor, which does not provide a credible, substantial and specific utility to the polypeptide comprising SEQ ID NO:20 and fragment thereof. In addition, the disclosure of the post filing references are not taught in the application, which cannot be used to substantiate a credible, substantial and specific utility of the claimed invention. The statute requires such utility to be taught in the application at the time of filing. In the instant case, a laundry list of the possible function does not constitute credible, substantial and specific utility for the claimed invention. Consequently, as discussed in the previous action, since the polypeptide comprising SEQ ID NO:20 and fragments lacks utility, the binding compound to said polypeptide also lack utility. Therefore, this rejection is maintained.

Claim Rejections - 35 USC § 112

Claims 9-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In response to the written description rejection, Applicants argue that the claimed invention is drawn to binding compounds that specifically bind a polypeptide comprising SEQ ID NO:20 or fragments thereof. Therefore, there is adequate description for the claimed compounds.

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This argument has been fully considered but deemed unpersuasive. The claims are drawn to a binding compound comprising an antigen-binding site from a substantially pure or recombinant antibody which binds to any polypeptide that comprises SEQ ID NO:20 or fragment thereof. The genus of polypeptide potentially encompasses a large number of polypeptides that may not even relate to SEQ ID NO:20. For example, a polypeptide comprising a fragment of SEQ ID NO:20 may be a polypeptide with entirely different structure and function. As such, the binding compounds for those unrelated polypeptides also have distinct structure and function. The specification only disclose two antibodies for the rat OX2 receptor, presumably encoded by SEQ ID NO:2. The specification fails to describe any binding compounds specific to SEQ ID NO:20, polypeptide comprising SEQ ID NO:20, fragments of SEQ ID NO:20, or fusion proteins of SEQ ID NO:20. The specification also fails to teach what structural feature such antibodies or binding compounds must share for them to function as a binding compound as claimed. As such, the specification fails to describe a representative number of species by their complete structure or other identifying characteristics. Therefore, the written description requirement is not satisfied. This rejection is maintained.

Claims 9-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In response to the enablement rejection, Applicants argue that the claimed invention is drawn to binding compounds that specifically bind a polypeptide comprising SEQ ID NO:20 or fragments thereof. Applicants assert that there is no legal requirement requiring certain proof of

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the function of the claimed polypeptide if the specification discloses at least one method for making and using the claimed invention. Applicants further assert that since the specification discloses the complete target sequence for the human OX2 receptor and method of making and using the binding compounds that bind the receptor, the enablement requirement is satisfied.

The above arguments have been fully considered but deemed unpersuasive. The reasons for the non-enablement are discussed in detail in the office action mailed on 6/3/04. As discussed in the previous office action and above, the claimed invention encompasses a large number of binding compounds that binds to proteins of different structures and function. Although the complete sequence of SEQ ID NO:20 is disclosed, the claimed invention is not limited to a binding compound that binds to this polypeptide represented by SEQ ID NO:20. Furthermore, the 112 1st statute requires the specification to teach not only how to make but also how to use the claimed invention according to its embodiment. Although there is no requirement requiring certain proof of function of the claimed polypeptide, one of skilled in the art would not know how to use a binding compound which the polypeptide it binds to has no utility. As such, the specification fails to teach one skilled in the art how to make and use the claimed invention, and undue experimentation would be required. Therefore, this rejection is maintained.

Claims 9-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 9-23, the term “substantially pure” renders the claim indefinite because it is unclear what this term encompasses. In other words, how pure the binding compound would

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have to be to constitute the term “substantially pure.” As such, the metes and bounds of the claim cannot be established.

Regarding claims 13 and 14, the recitation of “the attached to a solid substrate” renders the claim indefinite because it is unclear what is attached to the solid substrate.

Claim Objections

Claim 22 is objected to because of the following informalities: the claim recites “some fragment thereof,” however, “fragment” should be in plural form. Appropriate correction is required.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine X Qian Ph.D.
Examiner
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PRIMARY EXAMINER